RVD2008-25

Re-evaluation Decision

Benzisothiazolin-3-one

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Overview

Re-evaluation Decision

After a re-evaluation of the antimicrobial benzisothiazolin-3-one, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing benzisothiazolin-3-one for sale and use in Canada.

An evaluation of available scientific information found that products containing benzisothiazolin-3-one do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of benzisothiazolin-3-one uses, new risk-reduction measures must be included on the labels of all products.

The regulatory approach for the re-evaluation of benzisothiazolin-3-one was first presented in Proposed Re-evaluation Decision PRVD2008-13, *Benzisothiazolin-3-one*, a consultation document.[1] This Re-evaluation Decision[2] describes this stage of PMRA's regulatory process for the re-evaluation of benzisothiazolin-3-one as well as summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2008-13. To comply with this decision, registrants of products containing benzisothiazolin-3-one will be informed of the specific requirements affecting their product registration(s) and of regulatory options available to them.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re evaluation activities and program structure.

Benzisothiazolin-3-one, one of the active ingredients in the current re-evaluation cycle, has been re evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of benzisothiazolin-3-one. In this decision, the PMRA took into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy).

The USEPA re-evaluated benzisothiazolin-3-one and published its conclusions in a 2005 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation of the related Proposed Re-evaluation Decision PRVD2008-13, *Benzisothiazolin-3-one*.

What Is Benzisothiazolin-3-one?

Benzisothiazolin-3-one is an antimicrobial used as a preservative in metalworking fluids, latex emulsions, aqueous-based paints and aqueous mineral slurries in industrial settings. It is also used as a formulant in a variety of other pesticide products as a material preservative.

Health Considerations

Can Approved Uses of Benzisothiazolin-3-one Affect Human Health?

Benzisothiazolin-3-one is unlikely to affect your health when used according to the revised label directions.

Exposure to benzisothiazolin-3-one may occur when it is added to the material being treated (e.g. paint or metalworking fluids) or while using the treated material (e.g. painting, machinist handling metalworking fluids). Exposure may also occur when it is used as a formulant in other end-use products, through food or residential use, e.g. pet products. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that benzisothiazolin-3-one was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Environmental Considerations

What Happens When Benzisothiazolin-3-one Is Introduced Into the Environment?

Benzisothiazolin-3-one is unlikely to affect non-target organisms when used according to the revised label directions.

The USEPA concluded that indoor uses of benzisothiazolin-3-one were not likely to result in unacceptable ecological risk to non-target organisms, based on minimal exposure potential, and did not conduct any quantitative ecological risk assessments. Similarly, the use of benzisothiazolin-3-one as a formulant occurs at no more than 0.1% of the formulation and is readily biodegraded in soil, greatly reducing the exposure potential for terrestrial and aquatic organisms. Runoff into surface water from the use of benzisothiazolin-3-one as a formulant was also expected to be low. The USEPA concluded that the reregistration of benzisothiazolin-3-one was acceptable and no mitigation measures were required. These conclusions apply to the Canadian situation, and no risk-reduction measures are required.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk reduction measures to protect human health. These directions must be followed by law. As a result of the re-evaluation of benzisothiazolin-3-one, the PMRA is requiring further risk reduction measures for product labels.

Human Health

- Additional protective equipment to protect handlers.

Appendix I lists all required label amendments.

Other Information

Any person may file a notice of objection[3] regarding this decision on benzisothiazolin-3-one within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html), or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

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[3] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Label Amendments for Products Containing Benzisothiazolin-3-one

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statement below.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers.

I) The following statement must be included in the PRECAUTIONS section.

> Wear a long-sleeved shirt, long pants and chemical-resistant gloves when handling this product.